HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M3695n

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-55

April 19, 1999

Nelson Vegas, President
Super Value Trading International, Inc.
10530 N.W. 26th Street
Suite F-203
Miami, Florida 33172

Dear Mr. Vegas,

On December 8, 1998, the Food and Drug Administration (FDA) conducted an inspection of your seafood importing facility, located at 10530 N.W. 26th Street, Miami, Florida. The investigator, Carlos W. Hernandez, documented for the second consecutive time, serious deviations from the seafood HACCP regulation in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of these deviations cause the seafood products being imported and stored by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). The following deficiencies were noted:

> The HACCP Plan from [redacted] fails to list [21 CFR 123.6(c)(1)] or control [21 CFR 123.6(b)] the drug, chemical and food additive (sulfite) hazards that are reasonably likely to be present in imported aquacultured shrimp.
>
> Your firm has failed to list and implement written product specifications designed to ensure that the aquacultured frozen shrimp is not adulterated, as required in 21 CFR 123.12(a)(2)(i).

In addition, the foreign processor's HACCP plan from [redacted] is not signed and dated, as required by 21 CFR 123.6(d)(1).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these and all deviations at your firm. Failure to achieve corrective action may result in further regulatory action without further notice. These actions may include seizure, injunction, or removal from the European Union (EU) list. Additionally, until FDA is satisfied that the above deficiencies have been corrected, no EU certificates will issue. FDA may also detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director
Florida District